REMARKS

There is no present litigation regarding the issued patent and there has been none before this date. This application has no requested changes in original drawings. This application has no requested changes in original specifications. This application has no requested changes in original claims. All original claims are being resubmitted and none are being canceled. New claims 23 through 61 are being submitted. All new claims are clearly supported by the original drawings.

New claims 23 - 27 essentially constitute alternative and more encompassing methods of claiming those aspects of the invention that were previously claimed in claims 1 - 22, and for foundation rest upon the same disclosure. Claims 28 - 32 address newly identified aspects of the invention, for which the necessary foundation in each case is set forth below.

New claims 28 - 32 fall into two classes, the first class (1) being those which claim the combination of (a) the hypodermic syringe and needle; (b) the needle point guard safety cap assembly; and (c) a protective sheath, since it is that combination that is pre-assembled and packaged for shipment; and the second class (2) relating to the hingedly interconnected aspect of the invention, that structure permitting a rotational method of fabrication that avoids any need for any inwardly directed movement of the fingers along the axis of the needle in the direction of the needle tip.

In the specification at Col. 3, lines 10 - 16, it is noted that

> The needle point cover is typically adapted to receive a typical needle sheath. As such, the needle point guard safety cap assembly typically can be installed prior to sheath installation and needle distribution. Needles can therefore be distributed with the needle point cover stowed distal the point and with the sheath covering the needle in the normal fashion.

Such recitation provides foundation for new claim 28, which likewise places the needle point cover "distal the point" (i.e., proximal to the syringe), and then the sheath distal to the needle point cover. That a combination of the syringe, a needle, and the needle point guard safety cap assembly are contemplated as a composite unit (i.e., the "needle-protected hypodermic syringe" of claim 28) is shown by the language at Col. 3, second last line, to Col. 4, line 1: "The present invention is designed to be installed prior to needle use. It typically would be installed on the needle or syringe prior to distribution." One error in the initial filing and prosecution of

this '397 patent was thus the failure to recognize that "the invention" actually encompassed that composite, and not merely the needle point guard safety cap assembly taken by itself. The additional recitations of claim 29 essentially replicate elements previously claimed, and for which adequate foundation was found in the prosecution and allowance of the set of claims in the issued patent.

The rotational assembly of the "needle-protected hypodermic syringe" of claim 28, such assembly being noted in claims 30 - 32, is described at Col. 4, lines 4 - as follows:

> To install the presently preferred embodiment of the needle point guard safety cap assembly, the syringe attachment member and the needle point cover must be rotated into position to receive the needle. The syringe attachment member and frame are flexibly coupled. The syringe attachment member or base cup **150** is therefore rotated approximately 90 degrees with respect to the frame **130** so that the needle can extend through the syringe attachment member **150** approximately parallel to the extended frame **130**.

As equivalently described from an opposite perspective, and perhaps giving a better picture of the steps that actually occur, one can say that when the base cup **150** has been placed onto the needle hub or syringe -- ". . . the needle point guard safety cap assembly **100** is adapted to be attached to the needle hub or syringe." (Col. 5, lines 26 - 28) — the frame 130, which as shown in Figs. 1 and 2 is initially disposed at an angle of 90 degrees to base cup 150, is rotated 90 degrees so as to become in alignment with base cup 150 and thus in alignment with the needle which can then pass therethrough. The specification text just quoted thus provides foundation for the recitations of claim 30 wherein the proximal end segment is rotated into a disposition that is colinear with said hypodermic needle, and of claim 32 with respect to the "rotational means" by which the composite as a whole is constructed. Foundation for the analogous process of bringing the needle point cover member into alignment with the needle, as recited in claim 31, is as follows (Col. 4, lines 13 - 15):

> Next, a lid or enclosing member **118**, which is flexibly coupled to the needle point cover **110**, is rotated to plug or enclose the cover **110**.

These last two text recitations, respectively addressing the rotation of frame 130 (with its cover 110) into alignment with base cup 150, and then the rotation of the lid or enclosing member 118 into alignment with cover 110, also provide the foundation for claim 33 that recites the rotational method of assembly of the needle-protected hypodermic syringe of claim 28.

New claims 34 through 60 relate mainly to the needle point cover as a subcombination.

It should be noted that in the original application serial No. 09/160,511 the original claims 12 and 13 were rejected on the patents to Jenkins, Hagen and Steyn. Original claims 12 and 13 were subsequently canceled from that application. It is nevertheless believed that the needle point cover has many aspects that are patentable over the prior art.

New claim 61 broadly covers the overall needle protective assembly but is believed to distinguish over the prior art by virtue of the mechanism for locking the extendable frame to the needle shaft.

Favorable action is solicited.

Respectfully submitted,

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